

## **REMARKS**

In order antedate the Salo et al. reference that was previously, and currently, relied upon by the Examiner as a basis for rejecting claims 27-63 of the present application, Applicants submitted a copy of two Invention Disclosures that were submitted to the Patent Department of the Assignee of the present application (St. Jude Medical AB) on September 17, 2003.

The Examiner stated the submitted Information Disclosure Statements are insufficient to establish a data of conception of the invention, because the Invention Disclosures, according to the Examiner, do not provide support for the claim limitation of "a time duration of a predetermined phase of diastole of the heart" as set forth in independent claims 27, 47 and 48. The Examiner stated one of ordinary reading the Invention Disclosures would not have been able to draft the claims of the present application. The Examiner stated "those claims being narrower than the Declaration."

The Examiner also stated that the submitted Invention Disclosures are insufficient to establish diligence from a date prior to the reduction of practice of the Salo et al. reference to either a constructive reduction to practice or an actual reduction to practice. The Examiner stated Applicants must provide evidence of diligence for the time span between September 17, 2003 and November 7, 2003.

The Examiner also stated the submitted Disclosures are insufficient to establish a reduction to practice of the invention in the United States or in a NAFTA or WTL member country. The basis for statement was the same as the first objection, namely that, according to the Examiner, the claim language as filed is narrower in scope than as illustrated in the Declaration.

All of these conclusions by the Examiner are respectfully traversed, for the following reasons.

The Invention Disclosure documents that were previously submitted explicitly disclose determining a state of DHF, or an extent of DHF, by measuring a time duration from the occurrence of peak blood flow velocity through the mitral valve of the heart, to the time of zero blood flow velocity through the mitral valve of the heart. In other words, this means a measurement is made of the time duration between the completely open position of the mitral valve can be completely closed position of the mitral valve. This is specifically claimed in claim 29.

Independent claim 27, from which claim 29 depends, refers, as noted above, to “a time duration of a predetermined phase of diastole of the heart.” It is a physiological fact that the mitral valve is closed during systolic contraction of the heart, in order to prevent the backflow of blood from the left ventricle to the left atrium. Therefore, it is also clear that the time defined in claim 29, from which the mitral valve is open to the time that the mitral valve closes, necessarily occurs during diastole. Therefore, the statement in claim 27 of “a time duration of a predetermined phase of diastole of the heart” is merely a generic description that encompasses the more specific time duration set forth in claim 29.

It has long been settled as a matter of law that when the invention in question is a class (genus), conception of a species within a genus may constitute conception of the genus. This statement of the law can be found, for example, in *Oka v. Youssefye*, 849 F.2d. 581, 584, 7 U.S.P.Q.2d 1169, 1171 (Fed. Cir. 1988); *Hoffman v. Schoenwald*, 15 U.S.P.Q.2d 1512, 1514 (BPAI 1990) and *Miller v. Walker*, 214 U.S.P.Q. 845, 847 (BPAI 1982).

Therefore, at a minimum, it was not correct for the Examiner to state that the Invention Disclosure documents do not establish a date of conception at least for claim 29 (and corresponding method claim 52). Moreover, in view of the aforementioned statement of the law that conception of a species is normally sufficient to establish conception of the genus, Applicants submit that conception of the subject matter of at least independent claims 27, 47 and 48 is established by the Invention Disclosure documents as well, as of September 17, 2003.

With regard to the Examiner's second objection to the Invention Disclosure documents, as failing to establish diligence for the time span between September 17, 2003 and November 17, 2003, it is not clear to the Applicants as to why the Examiner selected the second date. Nevertheless, the preparation and filing of a Swedish application based on the Invention Disclosure documents took place diligently, and within the normal time span for other applications in the St. Jude Medical AB Patent Department. This is established by the Declaration of Thomas Skagersten that is submitted herewith.

The last objection raised by the Examiner has essentially the same basis as the first objection, and is therefore overcome, at least with regard to claims 27, 29, 47, 48 and 52, based on the above arguments.

Additionally, claims 27-63 were rejected under 35 U.S.C. §102(b) as being anticipated by the Invention Disclosure documents, because the Examiner stated that these documents provide sufficient support to antedate the present application, and the Examiner stated that there is nothing on the face of those documents that indicates that they are not public documents.

The aforementioned Declaration of Thomas Skagersten provides evidence to refute the statement made by the Examiner that Invention Disclosure documents are public documents, and are therefore available for use as prior art against the subject matter of the present application. The Declaration of Thomas Skagersten provides evidence that those Invention Disclosure documents were at all times treated as confidential documents by St. Jude Medical AB, and were used only within the Patent Department of St. Jude Medical AB, until the time that they were submitted as Exhibits in the prosecution herein.

Moreover, Applicants respectfully submit it is inconsistent on the part of the Examiner to accept the statements made in the previously-submitted Declaration regarding the content of those Invention Disclosure documents for the purpose of making a prior art rejection, but not to accept those statements for the purpose of antedating the Salo et al. reference. The factual content of the Invention Disclosure documents either does or does not disclose all of the elements of the claimed invention. If the Examiner does not agree that the content of the Invention Disclosure documents does provide such factual support, then it is irrelevant whether the Examiner considers Applicants to have made an “admission” with regard to such disclosure. If the Examiner believes that Applicants’ so-called “admission” is factually incorrect or unsubstantiated, then the Examiner is not permitted to ignore those alleged “defects” in the “admission” in order to make use of the “admission” for some other purpose.

In any event, the Examiner’s inconsistent use of Applicants’ previous Declaration is rendered moot by the Declaration of Thomas Skagersten submitted herewith.

As noted above, claims 27-43 and 48-63 were rejected under 35 U.S.C. §102(e) as being anticipated by Salo et al. For the above reasons, the Salo et al. reference is not available as prior art with regard to at least independent claims 27, 47 and 48, and since the Salo et al. reference is not available with regard to those independent claims, it cannot be used as an anticipating reference for any of the claims respectively depending therefrom.

Moreover, in substantiating that rejection, the Examiner discussed claim 47, and therefore it appears that the Examiner intended to include claim 47 in that rejection.

Claims 44-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Salo et al. in view of Paul et al. Since the Salo et al. reference is not available for use as prior art against independent claim 27, from which claims 44-46 depend, it is not possible to substantiate a rejection of those claims based on the Paul et al. reference by itself.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

  
\_\_\_\_\_  
(Reg. 28,982)

SCHIFF, HARDIN LLP

**CUSTOMER NO. 26574**

Patent Department

233 South Wacker Drive, SUITE 6600

Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants